

OP 164.6

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S): Duponchelle et al.

SERIAL NO: 09/393,743

FILED: September 10, 1999

INVENTION: "BICARBONATE-BASED SOLUTION IN TWO PARTS FOR PERITONEAL DIALYSIS OR SUBSTITUTION IN CONTINUOUS RENAL REPLACEMENT THERAPY"



DOCKET NO.: DI-5417

GROUP ART UNIT: 1646

EXAMINER: Unknown

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HKO
6-5-00

INFORMATION DISCLOSURE STATEMENT TRANSMITTAL LETTER

Assistant Commissioner for Patents
Washington, D.C. 20231
S I R:

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FEB 1600/2900

Submitted herewith is an Information Disclosure Statement for consideration in the above-identified application. This Information Disclosure Statement is submitted:

- ☒ [X] Within three months (1) of filing date of a national application; (2) of date of entry of the national stage as set forth in 37 C.F.R. §1.491 in an international application; or (3) before the mailing date of a first Office Action on the merits, whichever occurs last. (No fee is required.)
- ☐ [] After the mailing date of a first Office Action but before (1) mailing of a final action under 37 C.F.R. §1.113; or (2) mailing of a notice of allowance under §1.311, whichever occurs first:
 - ☐ [] Payment of the fee set forth in 37 C.F.R. §1.17(p) accompanies this submission; or
 - ☐ [] The certification specified in 37 C.F.R. §1.97(e) is made below. (No fee is required.)
- ☐ [] After the mailing of (1) a final action under 37 C.F.R. §1.113; or (2) notice of allowance under 37 C.F.R. §1.311 whichever occurs first, but before payment of the issue fee. The statement specified in 37 C.F.R. §1.97(e) is made below. The Commissioner hereby is petitioned to consider the Information Disclosure Statement accompanying this submission. Payment for the Petition fee set forth in 37 C.F.R. §1.17(i)(1) accompanies this submission.
- ☐ [] The undersigned counsel for applicant(s) hereby states each item of information identified in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.
- ☐ [] The undersigned counsel for applicant(s) hereby states that no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the undersigned, after making reasonable inquiry, was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of the statement.
- ☐ [] A check in the amount of \$_____ to cover any required fee is enclosed.
- ☒ [X] The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Account No. 08-2290. *A duplicate copy of this sheet is enclosed for this purpose.*

Very respectfully,

HILL & SIMPSON
A Professional Corporation

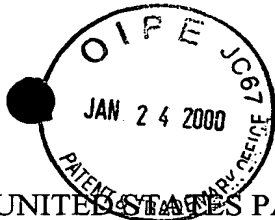
(Reg. No. 30,142)

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I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231 January 20, 2000.

Robert M. Barrett



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

INFORMATION DISCLOSURE STATEMENT

APPLICANT:	Duponchelle et al.	ATTY. DOCKET NO.:	DI-5417
SERIAL NO:	09/393,743	GROUP ART UNIT:	1646
FILED:	September 10, 1999	EXAMINER:	Unknown
INVENTION:	"BICARBONATE-BASED SOLUTION IN TWO PARTS FOR PERITONEAL DIALYSIS OR SUBSTITUTION IN CONTINUOUS RENAL REPLACEMENT THERAPY"		

Assistant Commissioner of Patents

Washington, D.C. 20231

S I R:

In accordance with the provisions of 37 C.F.R. 1.56, Applicants request that a citation and examination of the references identified below and on the attached PTO-1449 form, copies of which are enclosed herewith in accordance with 37 C.F.R. 1.98, be made during the course of examination of the above-mentioned application for United States Patent.

U.S. PATENT DOCUMENTS

<u>Patent Number</u>	<u>Patentee</u>	<u>Issue Date</u>
4,396,383	Hart	August 2, 1983
4,465,488	Richmond et al.	August 14, 1984
4,489,535	Veltman	December 25, 1984
4,584,176	Oliver et al.	April 22, 1986
4,630,727	Feriani et al.	December 23, 1986
4,959,175	Yatzidis	September 25, 1990

5,211,643	Reinhardt et al.	May 18, 1993
5,296,242	Zander	March 22, 1994
5,383,324	Segers et al.	January 24, 1995
5,431,496	Balteau et al.	July 11, 1995

FOREIGN PATENT DOCUMENTS

<u>Application Number</u>	<u>Country</u>	<u>Publication Date</u>
0 278 100	Europe	June 17, 1988
0 209 607	Europe	December 20, 1989
0 399 549 (Including Translation)	Europe	November 28, 1990
11-9659 (Laid-Open Publication Including Translation)	Japan	January 19, 1999
11-19178 (Laid-Open Publication Including Translation)	Japan	January 26, 1999
99/09953 (Abstract Only)	PCT	March 4, 1999
0 935 967 (Including Translation)	Europe	August 18, 1999

OTHER REFERENCES

Boen ST, *A Clinical Study of Factors Governing its Effectiveness*, Peritoneal Dialysis, p. 76, Van Gorcum & Co., Assen, The Netherlands (1959).

Feriani et al., *Short-Term Clinical Study with Bicarbonate-Containing Peritoneal Dialysis Solution*, Peritoneal Dialysis International, Vol. 13, pp. 296-301 (1993).

The Merck Index, 12th Ed., Merck Research Laboratories, Whitehouse Station, NJ, p. 1472 (1996).

Murphey et al., *Use of an Artificial Kidney*, J. Lab. Clin. Med., Volumn 40, pp. 436-444 (1952).

Odel HM et al., *Peritoneal Lavage as an Effective Means of Extrarenal Excretion. A Clinical Appraisal*, American Journal of Medicine, Vol. 9, 63-88 (1950).

Schambye et al., *The Cytotoxicity of Continuous Ambulatory Peritoneal Dialysis Solutions with Different Bicarbonate/Lactate Ratios*, Peritoneal Dialysis International, Vol. 13, Suppl. 2, Oct. 1-4, pp. S116-S118 (1994).

Schambye et al., *Bicarbonate- versus Lactate-Based CAPD fluids: A Biocompatibility Study in Rabbits*, Peritoneal Dialysis International, Vol. 12, pp. 281-286 (1992).

Simonsen et al., *Less Infusion Pain and Elevated Level of Cancer Antigen 125 by the Use of a New and More Biocompatible PD Fluid*, Advances in Peritoneal Dialysis, Vol. 12, pp. 156-160 (1996).

T.S. Ing. et al., *Bicarbonate-Buffered Peritoneal Dialysis*, The International Journal of Artificial Organs, Volume 8, No. 3, p. 121-124 (1985).

Zhou et al., *Effects of an Acidic, Lactate-Based Peritoneal Dialysis Solution and its Euhydric, Bicarbonate-Based Counterpart on Neutrophilic Intracellular pH*, Int. J. Artif. Organs, Vol. 16, No. 12, pp. 816-819 (1993).

REMARKS

Applicants also bring to the Patent Office's attention Applicants' copending patent application, U.S. Patent Application Serial No. 08/421,020, filed on April 12, 1995 and all of the references cited therein that are not cited above. To the extent that the Patent Office wants a copy of any of these references, Applicants respectfully request that the Patent Office contact Applicants' undersigned attorney and he will provide same.

Applicants look forward to early and favorable consideration of this matter.

Respectfully submitted,

(Reg. No. 30,142)

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CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231 on January 20, 2000.

